DEC 1 0 2001

510(K) Summary
Reference Check

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K013708

Submitters Name & Address:	Precision BioLogic Incorporated 900 Windmill Road, Suite 100 Dartmouth, Nova Scotia B3B 1P7 Canada
Contact Name:	Stephen L. Duff – Director of New Business Development Phone: 902-468-6422 ext. 224 Fax: 902-468-6421 Email: sduff@precisionbiologic.com
Preparation Date:	November 7, 2001
Device Name & Classification:	Reference Check Common Name: Normal Control Plasma Classification Name: Plasma, Control, Normal Regulatory Class II, 81 GIZ
Predicate Device:	Control Plasma N (K001256) Dade Behring Inc. Newark, Delaware 19714 USA
Device Description:	Reference Check is citrated human plasma collected from 20 or more carefully screened normal donors. Plasmas are pooled, buffered using 0.01M HEPES buffer, aliquoted and rapidly frozen.
Device Intended Use:	Reference Check is recommended for use in controlling the accuracy of quantitative hemostasis assays in the normal range.

Comparison to Predicate Device:

Parameter	Reference Check	Control Plasma N (K001256)
Intended Use	Assayed Control - Normal	Assayed Control - Normal
Analytes	Fibrinogen, Coagulation factors II, V, VII, VIII, vWF: Antigen, vWF: Ristocetin Cofactor, IX, X, XI, XII, XIII, prekallikrein, Protein C (antigen and activity), Protein S (activity, total and free), antithrombin (antigen and activity), Alpha-2 antiplasmin, plasminogen	PT, aPTT, TT, Batroxobin time, Fibrinogen, Coagulation factors, II, V, VII, VIII, IX, X, XI, XII, XIII*, vWF Ristocetin Cofactor, Antithrombin III, Protein C, Protein S*, Alpha-2 antiplasmin, C1-inhibitor*, Plasminogen, Lupus anticoagulants * not available in the US
Matrix	Reagent from human plasma (citrated human plasma collected from 20 or more carefully screened donors that is pooled and buffered using HEPES buffer).	Reagent from human plasma (obtained from pooled plasma collected from selected healthy blood donors and stabilized with HEPES buffer solution).
Format	Frozen	Lyophilized
Volume	1 mL per vial	1 mL per vial

Comments on Substantial Equivalence:

It is the opinion of Precision BioLogic Inc. that Reference Check is substantially equivalent to Control Plasma N (K001256), manufactured by Dade Behring Marburg GmbH, and currently marketed in the United States by Dade Behring Inc. This opinion is based on the following:

- Both products consist of pooled citrated normal human plasma
- Both products are assayed and provide reference ranges for fibrinolytic and coagulation parameters
- Both products are intended for use in the accuracy and control of assays for coagulation and fibrinolysis (i.e. hemostasis) in the normal range

Conclusion:

Reference Check is substantially equivalent to Control Plasma N.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Stephen Duff
Director of New Business Development
Precision Biologic
900 Windmill Road, Suite 100
Dartmouth, N.S.,
Canada

DEC 1 0 2001

Re: k013708
Trade/Device Name: Reference Check
Regulation Number: 21 CFR 864.5425
Regulation Name: Multipurpose system for in vitro coagulation studies
Regulatory Class: Class II
Product Code: GIZ
Dated: November 7, 2001
Received: November 8, 2001

Dear Mr. Duff:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K013708

Device Name: Reference Check

Indications for Use:

Reference Check is recommended for use in controlling the accuracy of quantitative hemostasis assays in the normal range. Reference Check is an assayed control for the following parameters in the normal range:

- Fibrinogen
- Factor II
- Factor V
- Factor VII
- Factor VIII:C
- vWF: antigen
- vWF: Ristocetin Cofactor
- Factor IX
- Factor X
- Factor XI
- Factor XII
- Factor XIII
- Prekallikrein
- Protein C: antigen
- Protein C: activity
- Protein S: activity
- Protein S: total
- Protein S: free
- Antithrombin: activity
- Antithrombin: antigen
- Alpha-2-antiplasmin
- Plasminogen

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K013708